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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/7554,387	06/29/00	FABRY	B H-3185-PCT/U

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HM12/0829

EXAMINER	
JIANG, S	
ART UNIT	PAPER NUMBER

1617

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/554,387	FABRY, BERND	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 June 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 11-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 11-30 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

This Office Action is in response to Applicant's response filed on June 26, 2001 in Paper No. 11. Currently, claims 11-30 are pending in this application.

Applicant's remarks filed on June 26, 2001 in Paper No. 11 with respect to the rejection of claims 11-12, 20-22, and 30 made under 35 U.S.C. 102(b) as being anticipated by Jandacek (3,865,939; PTO-1449 submitted June 29, 2000) for reasons of record stated in the Office Action dated February 26, 2001 have been considered and are found persuasive to remove this rejection.

Applicant's remarks filed on June 26, 2001 in Paper No. 11 with respect to the rejection of claims 11-12, 17, 20-22, and 27 made under 35 U.S.C. 102(b) as being anticipated by Hasegawa et al. (XP 002099834; PTO-1449 submitted June 29, 2000) for reasons of record stated in the Office Action dated February 26, 2001 have been considered and are found persuasive to remove this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939; PTO-1449 submitted June 29, 2000) and Hasegawa et al. (XP 002099834; PTO-1449 submitted June 29, 2000) in view of Miettinen et al. (EP 0594612B1; PTO-1449 submitted June 29, 2000), and Hidvegi (5,277,910) essentially for the reasons of record stated in the Office Action dated February 26, 2001 with respect to the rejection of Claims 13-16, 18-19, 23-26 and 28-29 made under 35 U.S.C. 103(a).

Jandacek discloses that phytosterols (synonymously phytostenols) have significant hypocholesterolemic activities. Jandacek also discloses that phytosterols such as β -sitosterol (synonymously β -sitostenol) along with saturated and unsaturated fatty acids having from 6 to 18 carbon atoms or glycerides of such fatty acids within the instant claimed compounds in an effective amount or combined with foodstuffs are useful for reducing serum cholesterol content in a mammal. See col.1 lines 5-14, col.2 lines 1-5, col.3 lines 27-28, col.4 lines 41-44, Table I, col.5 lines 17-31, Example I and claims 1, 3 and 6. Jandacek teaches broadly the usefulness of phytosterols such as β -sitosterol (synonymously β -sitostenol) along with saturated and unsaturated fatty acids having from 6 to 18 carbon atoms in the instant claimed method. Jandacek further teaches that the concentration level of phytosterols and saturated and unsaturated fatty acids having 6 to 18 carbon atoms in the hypocholesterolemic composition should be about 2.0 to about 6.0 wt.% and 0.5 to 15 wt.%, respectively, within the instant claims. See claim 1 and col.5 lines 17-23.

Hasegawa et al. teaches that the particular fatty acid, linoleic acid, and/or phytosterol including sitosterol (sitostenol) are useful for lowering the serum cholesterol in human mammals. Hasegawa et al. also teaches the vegetable oils have hypocholesteremic effects since they are high in linoleic acid and sitosterol. See the abstract.

Jandacek and Hasegawa et al. do not expressly disclose the employment of phytosterols such as β -sitostenol along with particular unsaturated fatty acids such as conjugated fatty acids having from 6 to 18 carbon atoms, e.g., conjugated linoleic acid, or the employment a particular carboxylic acid ester of a phytostenol or a β -sitosterol (β -sitostenol) having from 2 to 22 carbon atoms and up to about 3 double bonds together with a particular unsaturated fatty acid having from 6 to 18 carbon atoms such as a conjugated fatty acid having from 6 to 18 carbon atoms for use in methods of reducing serum cholesterol content. Further, Jandacek and Hasegawa et al. do not expressly disclose that the composition is encapsulated in gelatin.

Miettinen et al. teaches that β -sitosterol (β -sitostenol) and β -sitostanol and their fatty acid esters are known to be useful to lower serum cholesterol levels. See page 2 lines 5-7 and claim 1. Miettinen et al. further teaches that usable fatty acids therein contain approx. 2-22 carbon atoms such as fatty acids in vegetable oil, i.e., rapeseed oil within the instant claims. It is well known that rapeseed oil contains about 90% unsaturated fatty acids having one or more double bonds. See page 3 lines 44-45 and Example 1 on page 4. Miettinen et al. teaches broadly the usefulness of fatty acids

esters of β -sitosterol (β -sitostenol) and β -sitostanol containing approx. 2-22 carbon atoms specially unsaturated fatty acid esters in the instant claimed method.

Hidvegi discloses a pharmaceutical composition for lowering the blood-lipid level containing sitosterol and fatty acids such as linoleic acid formulated into gelatin capsules. See col.1 lines 59-65, col.2 line 37, col.3 line 38 and col.8 lines 18-28.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a phytosterol such as β -sitostenol along with a particular unsaturated fatty acid having from 6 to 18 carbon atoms such as a conjugated fatty acid having from 6 to 18 carbon atoms, e.g., conjugated linoleic acid, or employ a particular carboxylic acid ester of a phytostenol (phytosterol) or a β -sitosterol (β -sitostenol) having from 2 to 22 carbon atoms and up to about 3 double bonds together with a particular unsaturated fatty acid having from 6 to 18 carbon atoms such as a conjugated fatty acid having from 6 to 18 carbon atoms for use in methods of reducing serum cholesterol content and to make the composition encapsulated in gelatin.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a phytosterol such as β -sitostenol along with a particular unsaturated fatty acid having from 6 to 18 carbon atoms such as a conjugated fatty acid having from 6 to 18 carbon atoms, e.g., conjugated linoleic acid, or employ a particular carboxylic acid ester of a phytostenol (phytosterol) or a β -sitosterol (β -sitostenol) having from 2 to 22 carbon atoms and up to about 3 double bonds together with a particular unsaturated fatty acid having from 6 to 18 carbon atoms such as a conjugated fatty acid having from 6 to 18 carbon atoms for use in methods of reducing

serum cholesterol content because a phytosterol such as β -sitostenol along with an unsaturated fatty acid having from 6 to 18 carbon atoms including any conjugated fatty acids having from 6 to 18 carbon atoms, e.g., conjugated linoleic acid, are known to be useful in the instant claimed method for reducing serum cholesterol content in a mammal according to Jandacek. Therefore, one of ordinary skill in the art would have found it obvious to employ conjugated fatty acids having from 6 to 18 carbon atoms, e.g., conjugated linoleic acid, in the methods herein since it is well known that unsaturated fatty acids cover conjugated fatty acids. Hasegawa's teaching that particular fatty acid, linoleic acid, and/or phytosterol including sitosterol (sitostenol) are useful for lowering the serum cholesterol in human mammals further provides the motivation for the instant method. Moreover, fatty acid esters of β -sitosterol (β -sitostenol) or β -sitostanol having from 2 to 22 carbon atoms and up to about 3 double bonds including any fatty acids containing 2 to 22 carbon atoms and up to about 3 double bonds are useful for lowering serum cholesterol levels according to the teaching of Miettinen et al. Therefore, one of ordinary skill in the art would have reasonably expected that combining a conjugated fatty acid having from 6 to 18 carbon atoms and a fatty acid ester of a phytostenol (phytosterol) or a β -sitosterol (β -sitostenol) having from 2 to 22 carbon atoms and up to about 3 double bonds known useful for the same purpose in a composition to be administered would improve the therapeutic effect for reducing serum cholesterol content in a mammal. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) which renders the claims *prima facie* obvious. Additionally, one of ordinary skill in

the art would have been motivated to make the composition encapsulated in gelatin since the known pharmaceutical composition of Hidvegi for lowering the blood-lipid level containing sitosterol and fatty acids such as linoleic acid herein is formulated into gelatin capsules.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Applicant's remarks filed on June 26, 2001 in Paper No. 11 with respect to the rejection of claims 13-16, 18-19, 23-26 and 28-29 made under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939; PTO-1449 submitted June 29, 2000) and Hasegawa et al. (XP 002099834; PTO-1449 submitted June 29, 2000) in view of Miettinen et al. (EP 0594612B1; PTO-1449 submitted June 29, 2000), and Hidvegi (5,277,910) for reasons of record stated in the Office Action dated February 26, 2001 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed composition and methods over the prior art for the following reasons.

Jandacek teaches broadly the usefulness of phytosterols such as β -sitostenol along with saturated and unsaturated fatty acids having from 6 to 18 carbon atoms including any conjugated fatty acids having from 6 to 18 carbon atoms, e.g., conjugated linoleic acid, in the instant claimed method. Therefore, one of ordinary skill in the art would have reasonably expected that phytosterols such as β -sitostenol together with a conjugated fatty acid having from 6 to 18 carbon atoms would be useful in the instant claimed method for reducing serum cholesterol content in a mammal.

Applicant asserts that the Examiner has failed to establish a *prima facie* case upon the cited references since the Examiner fail to show three criteria for a *prima facie* case. Applicant further asserts that none of the cited references, nor a combination teaches or suggests each and every element of the claimed invention. Applicant's arguments are not found persuasive for the following reasons. First, the employment of a phytosterol such as β -sitostenol along with any unsaturated fatty acid including a conjugated fatty acid having from 6 to 18 carbon atoms is known to be useful in methods of reducing serum cholesterol content according to Jandacek. Moreover, Miettinen et al. teaches broadly the usefulness of fatty acids esters of β -sitosterol (β -sitostenol) and β -sitostanol containing approx. 2-22 carbon atoms and up to about 3 double bonds in the instant claimed method for reducing serum cholesterol content in a mammal. Hasegawa's teaching that the particular fatty acid, linoleic acid, and/or phytosterol including sitosterol (sitostenol) are useful for lowering the serum cholesterol in human mammals provides further motivation for the instant method. Therefore, one of ordinary skill in the art would have reasonably expected that combining a phytosterol and the particular unsaturated fatty acid, a conjugated fatty acid having from about 6 to about 24 carbon atoms, or a ester of a phytostenol (phytosterol) such as a ester of β -sitosterol (β -sitostenol) carboxylic acid having from 2 to 22 carbon atoms and up to about 3 double bonds known useful for the same purpose in a composition to be administered would improve the therapeutic effect of the combination composition for reducing serum cholesterol content in a mammal. Since all active composition components herein are known to useful to reduce serum cholesterol content in a

mammal, it is considered *prima facie* obvious to combine them into a single composition to form a third composition useful for the very same purpose, e.g., the treatment for reducing serum cholesterol content in a mammal. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Applicant's remarks regarding the teaching of Hidvegi have been considered but are not persuasive. The Hidvegi reference has been cited by the examiner primarily for its teaching that a pharmaceutical composition for lowering the blood-lipid level containing sitosterol and fatty acids similar to the composition herein, is known to be formulated into gelatin capsules. Therefore, one of ordinary skill in the art would have found it obvious to formulate the instant composition also comprising sitosterol and fatty acids into gelatin capsules. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145. Hidvegi has been cited by the Examiner as part of a combination rejection herein.

Therefore, the three criteria for a *prima facie* case are met for the instant case based on above discussion.

Applicant's data of Examples and Table 1 in the specification at pages 8-9 herein have been fully considered with respect to the obviousness of the claimed invention but are not deemed persuasive. Note that lauric acid in lauric acid β -sitostanol ester or lauric acid β -sitostenol ester employed in the test herein is not even an unsaturated

carboxylic acid (having no double bond) which is not a conjugated fatty acid. Thus, these two compounds are not within the scope of the claimed invention. Therefore, the results on these two compounds are not relevant to the nonobviousness of the claimed invention. The results on the tests of the employment of β -sitostenol or β -sitostanol combined with conjugated linoleic acid in the composition in the composition shown in Table 1 in the specification applied to rats have been fully considered but are not deemed persuasive as to unexpected results over the prior art because the results from the test on the employment of β -sitostenol or β -sitostanol combined with conjugated linoleic acid in the composition do not show any additive effects on reducing the cholesterol content in rats after 12 hours. After 24 or 48 hours the results merely demonstrate less than additive therapeutic effects of β -sitostenol and conjugated linoleic acid in the composition on serum cholesterol levels in rats. Further, the specification provides no side-by-side comparison between the employment of unconjugated fatty acids and conjugated fatty acids with β -sitostenol or β -sitostanol to clearly demonstrate any possible unexpected supra additive effects for the combination over the cited prior art. Moreover, the tests herein merely employ the combination of two particular phytostenols, β -sitostenol or β -sitostanol in combination with the particular conjugated fatty acid, conjugated linoleic acid. Thus, the evidence in the testing is not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range. See MPEP § 716.02(d). Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. See MPEP §

716.02(c). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
August 27, 2001

Minna Moezie
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